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INFO RUCPDOC/DEPT OF COMMERCE WASHINGTON DC
RUEHBR/AMEMBASSY BRASILIA 0052
RUEHBU/AMEMBASSY BUENOS AIRES 0007
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E.O. 12958: DECL: 2019/10/21 TAGS: <u>ETRD KIPR EIND EC</u>

SUBJECT: Presidential Decree on Compulsory Licensing Expected Soon

REF: QUITO 998

CLASSIFIED BY: Heather Hodges, Ambassador, State, Exec; REASON: 1.4(B), (D)

- 11. (SBU) Summary. President Correa appears set to issue within days a presidential decree to pave the way for compulsory licensing of patented pharmaceutical products. Local representatives of international pharmaceutical companies point out that a presidential decree is not legally required for the government to proceed with compulsory licenses, and worry that a decree will make it more difficult for the GoE to moderate its stance. The Ambassador raised U.S. concerns about this issue on October 19 with three key GoE officials in the Ministries of Foreign Affairs and Production, and EmbOffs are in close contact with industry representatives. End Summary.
- 12. (U) In his October 17 television address, President Correa expanded on his earlier threats to annul pharmaceutical patents (ref A) and noted his intention to publish a presidential decree early this week. Correa said he plans to initially issue compulsory licenses for all medicines, and then the policy will be applied to agrochemicals and other types of products that could be considered as public goods. Correa claimed international treaties allow Ecuador to establish compulsory licenses and described the GoE as a pioneer in implementing this policy in which knowledge is treated as a public good.
- 13. (C) In an October 15 meeting, Maria del Carmen, Executive Director of IFI a local chamber representing international R&D pharmaceutical companies, told Econoff and Commercial Assistant that a presidential decree on compulsory licensing of patented pharmaceutical products had been drafted, but that the content was not yet final. According to del Carmen's sources, the decree is expected to have two main provisions declaring: 1) access to medicines as a "public interest," and 2) all patented pharmaceutical products are subject to potential compulsory licensing. A third provision requested by local industry to allow importation of products under compulsory license was reportedly rejected by President Correa because it did not promote local production. However, Andres Ycaza, the head of Ecuador's Intellectual Property Institute, said in an October 19 El Universo article that if local manufacturing of a product under compulsory license was not possible, copies could be imported.

- 14. (C) Local representatives of U.S. and other international R&D pharmaceutical companies have identified and been in contact with potentially sympathetic ministries. They see as allies the Minister of Health Caroline Chang, Coordinating Minister for Production Nathalie Cely, and Coordinating Minister for Social Development Jeanette Sanchez. IFI has been told that these ministers have tried to explain to Correa the potential negative implications for economic development and the health system of issuing wholesale compulsory licenses, but he has rejected their arguments. Minister of Health officials are reportedly concerned they will be involved in enforcing any compulsory license and worry about the quality of copies. [Copies of patented pharmaceutical products are already pervasive in Ecuador and there have been problems with some not containing the active ingredient(s) of the patented product.] According to IFI, Chang is looking into financial irregularities and business dealings of some of the local producers in an attempt to gain some leverage and better understand their true objectives.
- 15. (C) On October 19, the Ambassador took advantage of a previously schedule meeting at the MFA to express concern over the issue with three key GoE interlocutors on economic policy. The Ambassador spoke at length with Technical Secretary Mauricio Pena of the Coordinating Ministry for Production (second to Minister Cely). Pena claimed not to have details on the President's plan, but said Correa was being motivated by an interest in gaining access to medicine and that the Ministry of Health was in charge of the issue. In her meeting with MFA Vice-Minister for Trade Julio

Oleas, the Ambassador said that while not delivering official points, she wanted to register Washington's concern with the GoE's plans for compulsory licensing as expressed by President Correa. Oleas responded candidly that it was a presidential, political decision and that now the government would have to figure out what to do. The Ambassador noted the IPR eligibility requirements of unilateral trade programs such as the Andean Trade Promotion and Drug Eradication Act and the Generalized System of Preferences. Oleas said he was also aware that the issue is covered in provisions of various international treaties and directed Pena to gather more details about the President's plan and forward to the Mission. Later, in response to urging by MFA Under Secretary for Bilateral Affairs Jorge Orbe that Ecuador and the United States develop a closer relationship through our Bilateral Dialogue process, the Ambassador pointed to the potential IPR issue as a serious problem.

COMMENT AND REQUEST

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16. (SBU) Despite Pena's claim that Correa's principal interest is access to medicine, we believe that his primary objective is promotion of local production, both on ideological grounds and possibly in response to specific requests by close associates in the local pharmaceutical industry. Among those close associates are Renato Carlo, President of the Chamber of Small Industries in Guayaquil and former President of ALFE, the association of local pharmaceutical producers, and the Ayala family (Rafael and Mauricio) who own Farmayala. Both allegedly contributed financial resources to President Correa's presidential campaign and Carlo is also a close friend from school. Econ and FCS officers continue to consult with representatives of U.S. pharmaceutical companies and have suggested they present President Correa with data that would help dispel his misperceptions regarding the extent to which wholesale compulsory licensing will yield a substantial increase in local production. The Embassy has also reached out to other diplomatic missions and conveyed an interest in collaborating. Although concerned, neither the French nor the Swiss Missions have yet approached the GoE on the issue. According to our contact at the French Embassy, the local EU delegation is calling a meeting next week with representatives of Member States to devise a common

approach. While not a member of the EU, the Swiss Embassy expects to join the EU meeting next week. The major French pharmaceutical companies in Ecuador are Sanofi-Aventis and Salvie; the Swiss companies are Roche and Novartis. The German Mission did not convey a high level of interest in pursuing the issue with the GoE. We will follow up with the British Mission over the next couple days. HODGES